



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

FEE

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: D444672; **FILE SYMBOL No.:** 71910-RN; **PRODUCT NAME:** Zecken Rollen Tick Tubes; **DECISION No.:** 534729; **PC Code(s):** 109701; **ACTION CODE:** R300; **FOOD Use:** No; **COMPANY:** Thermacell Repellents Incorporated

DATE OUT: December 12, 2017

SUBJECT: End Use Product Chemistry Review
Product Name: Zecken Rollen Tick Tubes

FROM: Shyam Mathur, Ph. D
Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB) /RD (7505P)

TO: Helen Hull-Sanders / Michael Walsh, RM 11; I-V Branch 2 / RD (7505P)

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product Zecken Rollen Tick Tubes. The registrant has submitted a CSF for basic formulation and an alternate CSF #1 (both dated October 5, 2017) and the supporting group A & group B product chemistry data with MRID No(s). 50410001. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 56783-1. CITAB has been asked to determine the acceptability of the proposed basic & alternate CSF's and the supporting product chemistry data and also determine similarity to the registered product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Permethrin (7.40%)
2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes give the registration number of the cited product.

EPA Reg. No: 56783-1
3. All of the source materials of the active ingredient are derived from registered sources- [X] Yes [] No
4. All inert ingredients have been screened by CITAB (Inert group) and found to be approved for the proposed labeled uses.

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5. Confidential Statement of Formula(s):

☒ Basic - Dated: 10-05-2017; Re-submitted - Dated:

☒ Alternate CSF #1 – Dated: 10-05-2017; Re-submitted alt CSF – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☒ Yes; ☐ No; ☐ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredients)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA
Acid Equivalent: ☐ Yes ☒ NA
acid equivalent =

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA
Methanol at > 4%: ☐ Yes ☒ No ☐ NA
Sodium nitrate/Sodium nitrite ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes; ☐ No

Note: The product label contains the required warning.

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

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7. Group A: Product Chemistry Data submitted

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	50410001
830.1600	Description of materials used to produce the product		X		A	50410001
830.1650	Description of formulation process		X		A	50410001
830.1670	Discussion on the formation of impurities		X		A	50410001
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Basic CSF dated 10-05-2017
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	50410001 HPLC-UV (215 nm) with IS calibration. Method validation provided. Submitted with storage stability study.

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

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8. Group B: Product chemistry data submitted

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Solid as loose cotton at 20°C	A	50410001
830.6315	Flammability	Combustible, contains cotton as substrate ¹	A	50410001
830.6316	Explosability	Does not contain any explosive ingredient	A	50410001
830.7000	pH	Non-dispersible in water	NA	50410001
830.7300	Density (units)	0.05 g/cc at 25°C	A	50410001
830.7100	Viscosity	TS is a solid	A	50410001
830.6317	Storage stability	Stable for 14 days at 54°C when stored in cardboard containers	A	50410001
830.6320	Corrosion characteristics	The product is a cardboard tube containing permethrin-dosed cotton. After 2 weeks at 54°C, the color of the cardboard and cotton were unchanged. The label became notably wrinkled on the outside of the cardboard after 2 weeks at 54°C.	A	50410001
830.6314	Oxidation/reduction	Does not contain any oxidizing and reducing agents	A	50410001

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1. United Nations Economic Commission for Europe (UNECE) Transport Guideline method for evaluating flammability of solids.

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CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No. 56783-1) from Product chemistry view point

- ☒ Similar
☐ Not similar, give reasons:
☐ Not Applicable

B. Confidential Statement of formula

1. Basic CSF (dated: 10-05-2017)
☒ Acceptable
☐ Not Acceptable:
☐ Not Applicable
2. Alternate CSF (dated: 10-05-2017)
☒ Acceptable
☐ Not Acceptable:
☐ Not Applicable

C. Group A Product Chemistry Data

- ☒ Acceptable
☐ with the exception of the guideline:
☐ Not acceptable
☐ Not required
☐ Data cited

D. Group B Product chemistry data

- ☒ Acceptable
☐ Not acceptable
☐ Acceptable with the exception of the guidelines
☐ Not required
☐ Data cited for the guidelines
☐ Waiver requests: Acceptable ☐; Not Acceptable ☒; Not Applicable ☐

E. Product Label/Draft Label: Recommendations – Yes ☐; No ☒

Note: The product label already has the required warning as per requirement of 40CFR§156.78

